AUG 1 3 2001

K012213

510(k) Summary
for
American Dental Technologies
Dental Operative Units

1. SPONSOR

American Dental Technologies
5555 Bear Lane
Corpus Christi, Texas 78405

Contact Person: John Vickers
Telephone: 361-289-1145

Date Prepared: July 3, 2001

2. DEVICE NAME

Proprietary Name:	Gulliver and Classe A Dental Operative Unit
Common/Usual Name:	Dental Operative Unit
Classification Name:	Dental Operative Unit with Accessories

3. PREDICATE DEVICES

Sirona Dental Systems Sirona C8 (K983242).

4. DEVICE DESCRIPTION

The American Dental Technologies Dental Operative Units are standard electrical or pneumatically operated dental operative units that will be available in two product lines, the Gulliver and the Classe A, and several models. Both the Gulliver and Classe A Dental Operative Units consist of the following major components:

- Patient Treatment Chair
- The Dentist's Instrument Board
- Assistants Board
- Cuspidor/Water system
- Overhead Dental Light

5. INTENDED USE

The Gulliver and Classe A Dental Operative Units are intended to supply power to and serve as a base for dental devices and accessories.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The American Dental Technologies Gulliver and Classe A Dental Operative Units and Accessories are substantially equivalent to the Sirona Dental Systems C8. The American Dental Technologies Gulliver and Classe A Dental Operative Units and the Sirona C8 have the same intended use.

The proposed and predicate devices use similar components, and are similar in design, characteristics, and mode of operation. Both systems include a chair, dentist's instrument board, cuspidor, assistant's board, dental light, and footswitches for control of the various functions.

7. PERFORMANCE TESTING

The American Dental Technologies Dental Operative Units comply with the requirements of EN 60601-1 and 60601-1-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2001

Mr. Donald J. Sherratt
Medical Stream Director
American Dental Technologies, Incorporated
C/O Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K012213
Trade/Device Name: Gulliver and Classe A
Regulation Number: 872.6640
Regulatory Class: I
Product Code: EIA
Dated: August 3, 2001
Received: August 7, 2001

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012213

Device Name: American Technologies Gulliver and Classe A Dental Operative Units

Indications For Use:

The American Dental Technologies Dental Operative Units are intended to supply power to and serve as a base for dental devices and accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012213

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)